

REMARKS

I. Pending claims

Claims 1, 2, 10, 11, 30, and 43-57 are pending in the application. Claims 45-57 are newly added, and are identical to original claims 29 and 31-42, respectively, which were canceled at the time the application was filed. Claims 3-9, 12-15, and 27-28 have been canceled. Specifically, newly added claims 46, 48, 51-52, and 54-57 are identical to originally filed claims 31, 33, 36-37, and 39-42, respectively, and are drawn to antibodies to SEQ ID NO:1. Accordingly, Applicants respectfully submit that claims 46, 48, 51-52, and 54-57 should be placed in Group IV.

Newly added claims 45, 47, 49-50, and 53, are identical to originally filed claims 29, 32, 34-35, and 38, respectively, and represent methods of using the claimed antibodies.

Applicants expressly do not disclaim the subject matter of any invention disclosed herein which is not set forth in the instantly filed claims. Applicants reserve the right to prosecute the non-elected claims in subsequent divisional applications. No new matter is added by any of these amendments.

II. Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 1-2) drawn to a polypeptide.

Group II (claims 3-7, 9, and 11-12) drawn to DNA.

Group III (claim 8) drawn to transgenic organisms.

Group IV (claims 10 and 30) drawn to antibodies.

Group V (claims 13-15) drawn to methods of detecting DNA.

Group VI (claim 27) drawn to methods for screening a compound for effectiveness in altering expression.

Group VII (claim 28) drawn to methods of assessing toxicity of a test compound.

Group VIII (claim 43) drawn to methods of detecting a polypeptide.

Group IX (claim 44) drawn to methods of purifying a polypeptide.

Applicants hereby elect, **with traverse**, to prosecute Group IV, which corresponds to claims 10, 30, 46, 48, 51-52, and 54-57, drawn to antibodies to SEQ ID NO:1. Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications. Applicants traverse the Restriction Requirement for at least the following reasons.

Applicants respectfully submit that there is minimal additional burden on the Examiner to examine the antibody claims of Group IV together with claim 43 (Group VIII), drawn to methods of detecting a polypeptide, claim 44 (Group IX), drawn to methods of purifying a polypeptide, and new claims 45, 47, 49, 50, and 53, drawn to methods of using the claimed antibodies. The method claims of Groups VIII and IX, and newly added claims 45, 47, 49-50, and 53, recite a product (i.e., an antibody) which is of the same scope as the claimed antibodies being searched by the Examiner. Thus, it would pose no undue burden on the Examiner to examine these method claims since a search of the prior art to determine the novelty of the claimed antibodies would substantially overlap with a search of the prior art to determine the novelty of the method claims.

Moreover, upon allowance of the claims of Group IV, claims 43, 44, 45, 47, 49-50, and 53 should be rejoined and considered, in accordance with the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Further, Applicants respectfully submit that there is minimal additional burden on the Examiner to examine claim 11, drawn to polynucleotides, since claims directed to "polynucleotide inventions" have already been issued in the parent case, which is now U.S. Patent No. 5,955,312. In addition, Applicants respectfully submit that there is minimal additional burden on the Examiner to examine claim 1, drawn to polypeptides of SEQ ID NO:1, since claims directed to "polypeptide inventions" have already been issued in the parent case, which is now U.S. Patent No. 6,280,733. For the Examiner's convenience, the issued claims are reproduced below.

U.S. Patent No. 5,955,312:

1. An isolated and purified polynucleotide fragment encoding the amino acid sequence of SEQ ID

NO:1.

2. A hybridization probe comprising the polynucleotide fragment of claim 1, and a detectable label.
3. An isolated and purified polynucleotide sequence comprising SEQ ID NO:2.
4. A polynucleotide fragment which is fully complementary to the polynucleotide sequence of claim 1.
5. A hybridization probe comprising the polynucleotide fragment of claim 4 and a detectable label.
6. An expression vector containing the polynucleotide fragment of claim 1.
7. An isolated host cell containing the expression vector of claim 6.
8. A method for producing a polypeptide comprising the amino acid sequence of SEQ ID NO:1, the method comprising the steps of:
 - a) culturing the host cell of claim 7 under conditions suitable for the expression of the polypeptide; and
 - b) recovering the polypeptide from the host cell culture.

U.S. Patent No. 6,280,733:

1. A purified polypeptide comprising an amino acid sequence as shown in SEQ ID NO:1.
2. An isolated polypeptide of claim 1, consisting of a sequence as shown in SEQ ID NO:1.
3. A composition comprising the polypeptide of claim 1 and a pharmaceutically acceptable excipient.
4. A method for screening a compound for effectiveness as an agonist of a polypeptide of claim 1, the method comprising:
 - a) exposing a sample comprising a polypeptide of claim 1 to a compound, and

b) detecting agonist activity in the sample.

5. A method for screening a compound for effectiveness as an antagonist of a polypeptide of claim 1, the method comprising:

a) exposing a sample comprising a polypeptide of claim 1 to a compound, and

b) detecting antagonist activity in the sample.

6. A purified polypeptide comprising an amino acid sequence having at least 90% sequence identity to an amino acid sequence shown in SEQ ID NO:1, and wherein said polypeptide binds to microtubules.

7. A biologically-active fragment of a polypeptide, wherein said polypeptide comprises an amino acid sequence as shown in SEQ ID NO:1, and wherein said biologically-active fragment binds to microtubules.

8. An immunogenic fragment of a polypeptide, wherein said polypeptide consists of an amino acid sequence as shown in SEQ ID NO:1, and wherein said immunogenic fragment generates an antibody that specifically binds to said polypeptide.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
INCYTE CORPORATION

Date: 06/27/03

Gina C. Nellesen
Gina C. Nellesen
Reg. No. 52,062
Direct Dial Telephone: (650) 843-7342

Date: June 27, 2003

Lori L. Kerber
Lori L. Kerber
Reg. No. 41,113
Direct Dial Telephone: (650) 845-4894

Customer No.: 27904
3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 3-9, 12-15, and 27-28 have been canceled.

Claims 45-57 have been added:

45. (New) A method for a diagnostic test for a condition or disease associated with the expression of hLC3 in a biological sample comprising the steps of:

- a) combining the biological sample with an antibody of claim 10, under conditions suitable for the antibody to bind the polypeptide and form an antibody:polypeptide complex; and
- b) detecting the complex, wherein the presence of the complex correlates with the presence of the polypeptide in the biological sample.

46. (New) A composition comprising an antibody of claim 10 and an acceptable excipient.

47. (New) A method of diagnosing a condition or disease associated with the expression of hLC3 in a subject, comprising administering to said subject an effective amount of the composition of claim 46.

48. (New) A composition of claim 46, further comprising a label.

49. (New) A method of diagnosing a condition or disease associated with the expression of hLC3 in a subject, comprising administering to said subject an effective amount of the composition of claim 48.

50. (New) A method of preparing a polyclonal antibody with the specificity of the antibody of claim 10 comprising:

- a) immunizing an animal with a polypeptide having the amino acid sequence of SEQ ID NO:1, or an immunogenic fragment thereof, under conditions to elicit an antibody response;
- b) isolating antibodies from said animal; and
- c) screening the isolated antibodies with the polypeptide, thereby identifying a polyclonal antibody which binds specifically to a polypeptide having the amino acid sequence of SEQ ID NO:1.

51. (New) An antibody produced by a method of claim 50.

52. (New) A composition comprising the antibody of claim 51 and a suitable carrier.

53. (New) A method of making a monoclonal antibody with the specificity of the antibody of claim 10 comprising:

- a) immunizing an animal with a polypeptide having the amino acid sequence of SEQ ID NO:1, or an immunogenic fragment thereof, under conditions to elicit an antibody response;
- b) isolating antibody producing cells from the animal;
- c) fusing the antibody producing cells with immortalized cells to form monoclonal antibody-producing hybridoma cells;
- d) culturing the hybridoma cells; and
- e) isolating from the culture monoclonal antibody which binds specifically to a polypeptide having the amino acid sequence of SEQ ID NO:1.

54. (New) A monoclonal antibody produced by a method of claim 53.

55. (New) A composition comprising the antibody of claim 54 and a suitable carrier.

56. (New) The antibody of claim 10, wherein the antibody is produced by screening a Fab expression library.

57. (New) The antibody of claim 10, wherein the antibody is produced by screening a recombinant immunoglobulin library.